

Serial No.: 10/640,853

Confirmation No.: 9178

Filed: August 13, 2003

For: ACTIVE AGENT DELIVERY SYSTEMS, MEDICAL DEVICES, AND METHODS

Remarks

The Office Action mailed August 25, 2009 has been received and reviewed. A Request for Continued Examination was filed on November 25, 2009. All previous claims having been cancelled, without prejudice, and claims 89-150 having been added, the pending claims are claims 89-150. Reconsideration and withdrawal of the rejections are respectfully requested.

Support for the new claims can be found throughout the originally filed application (e.g., page 14, line 23 through page 15, line 27, and page 32, line 27 through page 34, line 17), including the claims. No new matter has been added.

The 35 U.S.C. §102 Rejections

The Examiner rejected claims 1-18, 20-75, and 78-88 under 35 U.S.C. §102(b) as being unpatentable by Hossainy et al. (U.S. Patent No. 6,153,252). The Examiner rejected claims 1-18, 20-75, and 78-88 under 35 U.S.C. §102(b) as being unpatentable by Whitbourne et al. (U.S. Patent No. 6,110,483). The Examiner rejected claims 1-18, 20-75, and 78-88 under 35 U.S.C. §102(e) as being anticipated by Sirhan et al. (U.S. 2002/0082679 A1).

Without acquiescing to the Examiner's arguments, each of these claims has been cancelled solely in the interest of expediting prosecution, thereby rendering these rejections moot. Insofar as they may apply to the presently pending claims, they are respectfully traversed.

There is no teaching or suggestion in each cited document of a method of tuning the delivery of an active agent from an implantable medical device to a subject using a miscible polymer blend, with the recited relationships of solubility parameters between the polymers and active agent, at a predetermined amount over a period of time, which is not controlled by porosity in the miscible polymer blend. Furthermore, with respect to dependent claims 102, 117, 131, and 148, there is no teaching or suggestion in any cited document that delivery of the active agent occurs predominantly under permeation control.

M.P.E.P. §2131 states, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Also, as discussed in *Net MoneyIN, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1369 (Fed.Cir. 2008),

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because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements “arranged as in the claim” (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). That is, the Federal Circuit clarified that “[P]recedent informs that the ‘arranged as in the claim’ requirement applies to all claims and refers to the need for an anticipatory reference to show all of the limitations of the claims arranged or combined in the same way as recited in the claims, not merely in a particular order. The test is thus more accurately understood to mean ‘arranged or combined in the same way as in the claim.’” *Net MoneyIN*, 545 F.3d at 1370.

The Federal Circuit thus held that unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102. Accordingly, any rejection of the presently pending claims under 35 U.S.C. § 102 must fail.

Hossainy et al. teach processes for coating stents. Although Hossainy et al. teach certain types of polymers that encompass at least some of the polymers from which polymers of Applicants' miscible polymer blend may be selected, Hossainy et al. list over 30 classes of polymers that encompass innumerable species of polymers (arguably thousands if not hundreds of thousands or more) at columns 4 and 5. This list includes references to a handbook (*The Handbook of Biodegradable Polymers*), an encyclopedia (*The Encyclopedia of Polymer Science*), journal articles (in *Polymer Preprints* and *Journal of Biomaterials Research*), and patents (16 patents).

Hossainy et al. fail to expressly or inherently set forth the specific polymer combinations and active agents recited in the claims. For example, although Hossainy et al. may teach some of the same classes of polymers from which the first and second polymer may be selected, Hossainy et al. fail to teach the specific individual polymers from among the classes listed that one should select so that the second polymer will be miscible with the first polymer and possess the recited difference in solubility parameter with respect to the first polymer. That is, Hossainy et al. fail to

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teach, expressly or inherently, the step of receiving the second polymer selected to be miscible with the first polymer and to possess a solubility parameter that differs from the solubility parameter of the first polymer by no greater than $3 \text{ J}^{1/2}/\text{cm}^{3/2}$. Furthermore, Hossainy et al. fail to teach, expressly or inherently, the relationship between the active agent and the polymers of the miscible polymer blend as recited in each of Applicants' independent claims. Thus, Hossainy et al. cannot anticipate Applicants' claims. Applicants therefore respectfully request notification to this effect.

Whitbourne et al. teach polymer coatings for medical devices. Whitbourne et al. teach more than a dozen classes of polymers in columns 5 and 6, which, as in Hossainy et al., include innumerable species of polymers. Whitbourne et al. also includes polymers discussed in two encyclopedias (Concise Encyclopedia of Polymer Science and Engineering, and Kirk-Othmer Concise Encyclopedia of Chemical Technology).

Whitbourne et al. fail to expressly or inherently set forth the specific polymer combinations recited in the claims. The mere listing in Whitbourne et al. of general classes of polymers that includes classes similarly identified in Applicants' specification is insufficient to necessarily—i.e., inherently—teach the specific subpopulations of combinations recited in Applicants' claims. Whitbourne et al. fail to teach the specific individual polymers from among the classes listed in the Office Action that one should select so that the second polymer will be miscible with the first polymer and possess the recited difference in solubility parameter with respect to the first polymer.

Also, Whitbourne et al., like Hossainy et al., fail to teach, expressly or inherently, the step of receiving the second polymer selected to be miscible with the first polymer and to possess a solubility parameter that differs from the solubility parameter of the first polymer by no greater than $3 \text{ J}^{1/2}/\text{cm}^{3/2}$. Furthermore, Whitbourne et al. fail to teach, expressly or inherently, the relationship between the active agent and the polymers of the miscible polymer blend as recited in each of Applicants' independent claims. Thus, Whitbourne et al. cannot anticipate Applicants' claims. Applicants therefore respectfully request notification to this effect.

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Sirhan et al. teach luminal prosthetic devices that allow for controlled release of a therapeutic agent (Abstract). More than a dozen classes of suitable polymers are listed in paragraphs [0119] and [0120], including “mixtures, copolymers, and combinations thereof” for each set of polymers. Sirhan et al. describe certain classes and/or types of polymers that are identified in Applicants’ specification as classes and/or types from which polymers may be selected to form the particular subpopulation of miscible polymer blends recited in Applicants’ claims.

Sirhan et al. fail to expressly or inherently set forth the specific polymer combinations and active agents recited in the claims. Also, Sirhan et al. fail to teach, expressly or inherently, the step of receiving the second polymer selected to be miscible with the first polymer and to possess a solubility parameter that differs from the solubility parameter of the first polymer by no greater than $3 \text{ J}^{1/2}/\text{cm}^{3/2}$. Furthermore, Sirhan et al. fail to teach, expressly or inherently, the relationship between the active agent and the polymers of the miscible polymer blend as recited in each of Applicants’ independent claims. Thus, Sirhan et al. cannot anticipate Applicants’ claims. Applicants therefore respectfully request notification to this effect.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 1-18, 20-75, and 78-88 under 35 U.S.C. §103(a) as being unpatentable over Sirhan et al. (U.S. 2002/0082679 A1) in view of Van Krevelen (Properties of Polymers, 3rd ed., Chapter 7, 189-225). The Examiner rejected claims 1-18, 20-75, and 78-88 under 35 U.S.C. §103(a) as being unpatentable over Sirhan et al. (U.S. 2002/0082679 A1), in view of Coleman et al. (Specific Interactions and the Miscibility of Polymer Blends, Ch. 2: A Practical Guide to Polymer Miscibility, 1991; 49-156). The Examiner rejected claims 1-18, 20-75, and 78-88 under 35 U.S.C. §103(a) as being unpatentable over Hossainy et al. (U.S. Patent No. 6,153,252) in view of Van Krevelen (Properties of Polymers, 3rd ed., Chapter 7, 189-225). The Examiner rejected claims 1-18, 20-75, and 78-88 under 35 U.S.C. §103(a) as being unpatentable over Hossainy et al. (U.S. Patent No. 6,153,252) in view of Coleman et al. (Specific Interactions and the Miscibility of Polymer Blends, Ch. 2: A Practical Guide to Polymer

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Miscibility, 1991; 49-156). The Examiner rejected claims 1-18, 20-75, and 78-88 under 35 U.S.C. §103(a) as being unpatentable over Whitbourne et al. (U.S. Patent No. 6,110,483), in view of Van Krevelen (Properties of Polymers, 3rd ed., Chapter 7, 189-225). The Examiner rejected claims 1-18, 20-75, and 78-88 under 35 U.S.C. §103(a) as being unpatentable over Whitbourne et al. (U.S. Patent No. 6,110,483), in view of Coleman et al. (Specific Interactions and the Miscibility of Polymer Blends, Ch. 2: A Practical Guide to Polymer Miscibility, 1991; 49-156).

Without acquiescing to the Examiner's arguments, each of these claims has been cancelled solely in the interest of expediting prosecution, thereby rendering these rejections moot. Insofar as they may apply to the presently pending claims, they are respectfully traversed.

There is no teaching or suggestion in each cited document of a method of tuning the delivery of an active agent from an implantable medical device to a subject using a miscible polymer blend, with the recited relationships of solubility parameters between the polymers and active agent, at a predetermined amount over a period of time, which is not controlled by porosity in the miscible polymer blend. Furthermore, with respect to dependent claims 102, 117, 131, and 148, there is no teaching or suggestion in either cited document that delivery of the active agent occurs predominantly under permeation control.

Applicants' system includes polymers that are miscible, focusing on a solubility parameter difference of no greater than about $3 \text{ J}^{1/2}/\text{cm}^{3/2}$. On this point of miscibility between polymers and tuning the release rates of active agents, the Examiner's attention is directed to Lyu et al., Journal of Controlled Release, 102, 679-687 (2005), in which tunable diffusion of an active agent (dexamethasone) was achieved using a miscible polymer blend, but not with an immiscible polymer blend. See, for example, Figure 9.

Once again, while the specific disclosures of Sirhan et al., Whitbourne et al., and Hossainy et al. differ somewhat, the relevant disclosure for analysis of the rejections is the same: each document identifies a vast number of individual polymer species. Furthermore, the documents cited as secondary references (Van Krevelen and Coleman et al.) do not provide that

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which is missing from Sirhan et al., Whitbourne et al., and Hossainy et al. Consequently, unless otherwise specifically indicated, the remarks that follow apply to each rejection.

Applicants submit that while the combinations of cited documents describe classes of polymers that encompass at least some of the polymers from which polymers used to form the miscible polymer blends in Applicants' claims may be selected, they neither teach nor suggest the selection criteria for the recited combinations of polymers and active agents. The combinations of cited documents provide no blaze marks that would direct one skilled in the art to select polymers and active agents based on their miscibility and/or the recited differences in solubility parameter.

The subsets of polymer and active agent combinations to which Applicants' claims are drawn is small and specific in relation to all of the possible combinations encompassed by the disclosures of the combinations of cited documents and is undisclosed in the combinations of cited documents. Moreover, the combinations of cited documents provide no teaching or suggestion that would direct one skilled in the art to Applicants' claimed subset of polymer and active agent combinations from among the innumerable combinations described.

Applicants' position is supported by the decision of the Federal Circuit in *In re Baird*, 29 USPQ2d 1550 (1994), and, after *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), the rationale used by the Federal Circuit in *In re Baird* was reiterated in *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories Inc.*, 86 USPQ2d 1196 (Fed. Cir. 2008). The Federal Circuit reiterated that a claim cannot be rendered obvious by a prior disclosure that includes several unpredictable alternatives without some guidance to select features recited in the claim. The Federal Circuit contrasted a situation as presented in *KSR* (e.g., "a situation with a finite, and in the context of the art, small or easily traversed, number of options" 86 USPQ2d at 1201) with situations in which the path to the claimed subject matter is less direct. The Federal Circuit rejected the argument, based on language from *KSR*, that claims to a new drug were obvious in light of "a finite number of identified, predictable solutions." *Id.* The Federal Circuit noted that one skilled in the art, even if provided with a general class of compound from which to start, would not necessarily have chosen the starting compound selected by the patentee. *Id.*

In the present application, the combined teachings of the suggested combinations of documents describe innumerable polymer species, but provide no guidance to select polymers and an active agent in relation to one another, based on the criteria recited in Applicants' claims.

Applicants' position is further supported by a recent decision of the Federal Circuit. The Federal Circuit revisited the issue of the alleged obviousness of claimed subject matter in view of a generic disclosure that encompasses at least a portion of the claimed subject matter in *Süd-Chemie, Inc. v. Multisorb Technologies, Inc.*, 89 USPQ2d 1768 (2009). *Süd-Chemie, Inc.* involved a patent directed to a desiccant container made from a water-vapor-permeable, multilayered packaging material that included "compatible" polymeric materials, as the term "compatible" is defined in the specification of Süd-Chemie's patent. *Id.* at 1770. The patent was asserted against an alleged infringer, Multisorb, who argued that Süd-Chemie's patent was invalid as obvious over an earlier patent to Komatsu. The district court found that the polymeric materials in the Komatsu patent encompassed some of the "compatible" polymeric materials of Süd-Chemie's claims and granted summary judgment that Süd-Chemie's patent was invalid as obvious in view of the Komatsu patent. *Id.*

The Federal Circuit panel **REVERSED** the district court and critiqued the district court's analysis as follows:

Finally, claim 1 of the '942 patent requires that the inner surfaces of the microporous and laminate films be "comprised of compatible polymeric materials." The district court concluded that Komatsu teaches the use of compatible films because "[t]he Komatsu patent suggests the employment of the same materials claimed by the '942 patent to be 'compatible polymeric materials.'" It is true that Komatsu discloses the same general classes of materials that are identified in the '942 patent. Thus, both patents state that the microporous and laminate films can be made from polyethylene, polypropylene, and other polyolefinic materials. See Komatsu, col. 2, ll. 19-21; col. 3, ll. 12-15; '942 patent, col. 5, ll. 12-15, 47-50. However, in concluding that Komatsu teaches the use of compatible polymeric materials, the district court failed to acknowledge that the specified classes of materials comprise a large number of substances with quite different properties, and that various combinations of those materials can be compatible or incompatible depending on how they are assembled in layers to form the container.

Id. at 1772 (emphases added).

The Federal Circuit held that the district court erred in ruling that Süd-Chemie's patent was invalid as obvious over the Komatsu patent, disagreeing with the district court "with regard to its conclusion that Komatsu teaches the same materials on the container's inner surface as those claimed in [Süd-Chemie's] patent." *Id.*, at 1775.

The Federal Circuit's analysis in *Süd-Chemie* is directly applicable to the instant Application. The cited documents describe classes of polymers that may be blended, but those classes include innumerable species that have different properties, chief among those different properties are different solubility parameters. Thus, various combinations of members of the classes of polymers may possess the recited difference in solubility parameter or they may not, depending upon which members of the classes are selected.

Without guidance that directs one of ordinary skill in the art to miscible polymer blends and active agents having the recited differences in solubility parameter, the recitation of general classes of polymers and the general teaching that members of the classes may be combined does not render Applicants' claims obvious. The combinations of cited documents describe innumerable polymer species, but provide no guidance to select polymers and active agents in relation to one another and based on the criteria recited in Applicants' claims. Consequently, the obviousness analysis with respect to Applicants' claims is similar to the analysis by the Federal Circuit in these post-KSR cases. Applicants respectfully submit that the presently pending claims are not obvious in view of the combinations of cited documents. Applicants therefore respectfully request notification to this effect.

Amendment and Response
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Summary

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 1st day of December, 2009.

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